Report Title 48732801

2011 Insect Resistance Management (IRM) Compliance Assurance Program Report for Corn Borer-Protected Bt Corn, Corn Rootworm-Protected Bt Corn, Corn Borer/ Corn Rootworm-Protected Stacked and Pyramided Bt Corn

Data Requirement

Condition of Registration for:

Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, 67979-12, and 29964-3),
Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4),
Corn Borer/Corn Rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 524-576, 68467-6, 67979-8, 67979-13, and 29964-5),
Corn Borer/Corn Rootworm-Protected Pyramided Bt Corn (EPA Reg. Nos. 524-575, 524-581, 524-595, 67979-15, 67979-17, 68467-7, 68467-16)

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Report Completion Date

January 31, 2012

Registrant Submitting

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Project ID

CAP-2011

Volume 1 of 1

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GLP Compliance Statement

This report does not meet the U.S. EPA Good Laboratory Practice requirements as specified in 40 CFR Part 160, as it is not a study but a report summarizing information compiled from third-party, IRM Grower Surveys and third-party IRM On-Farm Assessments by the ABSTC.

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Ownership Statement

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Executive Summary

The 2011 Compliance Assurance Program (CAP) Report, compiled by the Agricultural Biotechnology Stewardship Technical Committee (ABSTC), describes industry-coordinated compliance assurance activities for insect resistance management (IRM) associated with Bt traits in corn that provide protection from corn borers and/or corn rootworms, including those products with stacked and pyramided traits[1], that require growers to plant a structured refuge. This report includes a summary of the 2011 results for the third-party[2] Grower Survey, third-party IRM On-Farm Assessments, and other ABSTC CAP activities.

A new enhanced CAP was implemented in 2011 and this is the first report under the new CAP requirements. Methodology changes to the IRM Grower Survey as well as the On-Farm IRM Assessments were implemented in accordance with revised registration terms and conditions issued by EPA. The CAP incorporates the broad portfolios of products that have structured refuge requirements, including reduced refuge products. The changes outlined here and discussed in detail in the body of the report, while necessary, preclude the direct comparison of data from the 2011 CAP report with data from previous CAP activities. The data in this report should therefore be considered the comparator for future CAP activities.

The IRM Grower Survey has been designed and conducted each year since 2000 by the independent marketing research firm, Market Probe, Inc. (St. Louis, MO). The Grower Survey results are a measure of adherence to refuge requirements designed to be representative of growers who plant the vast majority of Bt corn. In 2011, the methodology was revised and expanded to incorporate the broad portfolios of Bt corn products with differing refuge requirements. A statistically representative sample of growers was surveyed. The results from the Grower Survey are summarized below.

- Grower adherence to size requirements for all their corn borer-protected Bt corn fields[3]: 66%
- Grower adherence to size requirements for all their corn rootworm-protected Bt corn fields[4]: 72%
- Grower adherence to distance requirements for all their corn borer-protected Bt corn fields: 76%
- Grower adherence to distance requirements for all their corn rootworm-protected Bt corn fields: 61%

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[1] The use of a single toxin against a pest in combination with one or more single toxins for other pests is termed a stack. The use of multiple toxins against the same pest is termed a pyramid.

[2] A third party is defined for On-Farm Assessment purposes as a party other than the registrant, the grower or anyone else with direct interest in IRM compliance for Bt corn.

[3] Corn borer, with or without rootworm

[4] Corn rootworm, with or without corn borer

The Grower Survey found that 81% of corn borer-protected Bt corn fields and 70% of corn rootworm-protected Bt corn fields had some refuge within the required distance.

The objective of the On-Farm IRM Assessment program is to look for individual non-compliant growers and bring them back into compliance through the Phased Compliance Approach. Unlike the online IRM Grower Survey, the On-Farm Assessment program is not a statistical tool for measuring the level of adherence with the IRM requirements. Throughout the On-Farm Assessment process, identifying details of the assessed growers are kept confidential by the registrant contracting the assessment.

To comply with the terms and conditions of the Bt corn product registration extension as issued by the EPA, the enhanced CAP incorporates the following:

- Contract with independent third parties to perform on-farm assessments of adherence with refuge requirements.
- Focus the majority of the on-farm assessments in regions where the risk of resistance is greatest.
- Use available Bt sales records and other information to refine grower lists for on-farm assessments.

In 2011, a tiered IRM On-Farm Assessment process was implemented. Each member company independently reviewed available sales data for its Bt corn customers. On-farm assessments were conducted with growers who, according to these sales records, may have purchased little or no refuge seed to determine whether they were in compliance with refuge requirements and the extent of any deviations. As anticipated, this tiered On-Farm Assessment process identified more than three times as many non-compliant growers as in years past. In accordance with the CAP's Phased Compliance Approach, all growers who were found out of compliance in 2010 were contacted with additional educational materials and a follow-up re-assessment in 2011, which resulted in the majority complying with the IRM requirements during the 2011 growing season. The Phased Compliance Approach has again proven to be an effective mechanism to correct the vast majority of individual instances of non-compliance identified through the On-Farm Assessment program.

The ABSTC continues to enhance education to preserve the efficacy of the technology. Some key areas of focus include:

- The ABSTC is partnering with the National Corn Growers Association (NCGA) to ensure that NCGA's membership and networks are fully informed of refuge requirements and the CAP. One collaborative example of this is the inclusion of all structured refuge products in the NGFA IRM calculator. (www.irmcalculator.com).

- Registrants are implementing refuge requirement information on seed packaging, such as bags/tags, in 2011.
- Registrants are engaging with Cooperative Extension entomologists and other external educators to share key findings and key messaging.

Implementation of the enhanced CAP demonstrates the industry's commitment to Bt corn product stewardship so that growers can continue benefitting from Bt corn technologies.

Section I. Introduction

The 2011 CAP report describes the results of the industry-coordinated Bt corn IRM compliance assurance activities. These compliance activities are described in the most recent enhanced Bt corn IRM CAP – submitted by the ABSTC to the EPA on January 31, 2011 (MRID 48375101) in response to the 2010 amended registrations for Bt corn products. Core elements of the Bt corn IRM CAP are an anonymous Grower Survey used to measure adherence to the IRM requirements, and an On-Farm Assessment program that is used to look for individual growers who are out of compliance with refuge requirements and provide education and assistance to those found so that they are better able to follow refuge requirements.

With recent registrations of new Bt corn products, growers have more options from which to choose, and growers are able to plant multiple products with differing refuge requirements on their farms. In response to the increased complexity of product offerings and IRM requirements, a number of enhancements were made to the Grower Survey and On-Farm Assessment program:

- **CAP Enhancements**: some of the Bt corn IRM CAP enhancements resulted in changes to the On-Farm IRM Assessment methodology (e.g., focused assessments based on the registrant's refuge seed sales records and the resistance risk associated with geographical region, as opposed to more random grower selection).
- **Expanded Scope of Bt Corn Products (as shown in Appendix)**: historically, the industry-coordinated ABSTC CAP activities were limited to Bt corn products requiring a 20% refuge in the Corn Belt (50% refuge in the cotton region). In 2011, the CAP activities were expanded to include all Bt field corn products currently available, including reduced refuge products. This expansion resulted in changes to the survey methodology.
- **Third-Party Involvement:** On-Farm Assessments are now conducted by independent third parties.

These changes, while necessary, preclude the direct comparison of data from the 2011 CAP report with data from previous CAP activities. The data in this report should therefore be considered the comparator for future CAP activities.

Section II. Third Party IRM Grower Survey

1. Methodology

The 2011 IRM Grower Survey was designed and conducted by the same independent third-party organization as in previous years (Market Probe, St. Louis, MO). The objective of the IRM Grower Survey is three-fold: i) determine the level of adherence to the IRM requirements, ii) measure awareness of the IRM requirements, and iii) obtain grower feedback for continuous improvement of educational and compliance programs. As with previous Grower Surveys, the 2011 Grower Survey was designed to incorporate the following features:

- A sample size that allows for reasonable sensitivity in comparing results across regions.
- Focus on the primary corn production areas of the U.S. and on areas with the greatest potential for the development of insect resistance.
- Enables an assessment of the reasons, extent, and biological significance of deviations from the IRM requirements.
- Minimizes the potential for false positives or non-response bias.

Historically, the Grower Survey questioned growers about their planting practices for products with a 20% (50% in the cotton region) structured refuge requirement. The survey was designed in a way that grouped products into product categories of single trait corn borer-protected Bt corn, single trait corn rootworm-protected Bt corn and corn borer/corn rootworm-protected stacked Bt corn, and the level of adherence with the refuge requirements was determined on a product category basis. Growers planting Bt corn products not falling into one of these three categories (e.g., reduced refuge Bt corn products) were surveyed independently by individual Bt corn registrants.

For the 2011 IRM survey, the ABSTC member companies worked with Market Probe to design one survey that would include all Bt corn products on the market. Due to the large number of Bt corn products with differing trait combinations and refuge requirements now on the market, it was not practical to group products into the same categories as before. Market Probe therefore recommended that the survey be conducted based on individual Bt corn products. For example, growers were asked how much of each specific Bt corn product was planted on their farm, as opposed to the prior practice of asking how much of a particular product category was planted. Results were categorized based on the target pest (i.e. corn borer or corn rootworm) to improve the biological relevance of the findings.

Market Probe selected growers from among those who planted 200 or more acres of corn in the Corn Belt or planted 100 or more acres of corn in the cotton region. Respondents were required to: i) be actively involved in farming; ii) be the individual primarily responsible for decisions concerning seed purchase for their operation; and iii) not have worked for a farm chemical manufacturer, distributor or dealer, or for a seed company other than as a farmer/dealer, which also applied to family members.

Telephone interviews were used to identify a representative sample of growers willing to complete the Grower Survey. Qualified respondents were then directed to the internet, where the IRM questionnaire was available online (available June 20 – August 28, 2011). Once online, growers were prompted to respond to a series of questions about their Bt corn planting practices and awareness of IRM refuge requirements. This approach allowed the growers time to complete the survey at their pace, helping to ensure that they understood what was being asked, and allowed time for the growers to verify information by checking their planting records if necessary, prior to answering the questions. Grower Survey questions were written in such a manner that a grower may not have recognized that it was an IRM-related survey until after a significant amount of data had been collected. Grower Survey data were reviewed and tabulated by Market Probe to determine adherence to refuge requirements.

For all Bt corn products planted, the surveyed growers were asked about the size of refuge planted. To keep the survey from becoming unduly long, refuge distance-related questions were asked for up to three Bt products on a grower's farm. For those growers planting more than three Bt corn products, the survey prioritized the recently introduced products to ensure adequate representation of all products in the data set. For example, if a grower planted four Bt products, the survey would prompt the grower to answer questions about refuge size for all four products and questions about refuge distance for the three newest products. For determining adherence to distance requirements on a whole farm basis, data for growers who planted three or fewer products were included.

The Grower Survey questionnaire also included a series of questions designed to assess grower awareness of IRM requirements. Historically, this section included a series of aided and unaided awareness questions about the specific refuge size and distance requirements for the product categories. Due to the number of Bt corn products with differing trait combinations and refuge requirements now on the market, the ABSTC, with input from Market Probe, modified the awareness questions to focus on the need for refuge and availability of sufficient information to understand refuge requirements at the time of planting. It is the view of the ABSTC that due to the number of Bt corn products available today, growers should not be expected to memorize and recall specific refuge requirements for the products they planted. In fact, the ABSTC believes that growers should not attempt to memorize refuge requirements because such a practice undermines the long-standing advice from the EPA and registrants that growers must read and then follow all use directions. The addition of IRM information on seed packaging will help

to provide the refuge information at growers' fingertips when they begin to plant. The remaining questions, designed to evaluate the effectiveness of various IRM education programs, were revised to collect feedback on some of the new IRM education strategies.

The geographic representation desired was 900 growers from the Corn Belt and a minimum of 100 from the cotton region. This sample size, together with the survey prioritization strategy, was selected to ensure an adequate representation of all Bt corn products.

To address BPPD's request[5] to provide survey data on a regional basis, Market Probe assessed a statistically representative number of growers in three regions. These regions were defined by the ABSTC and conveyed to BPPD in the minutes of a May 21, 2009 meeting between BPPD and the ABSTC IRM Stewardship Subcommittee.[6] To obtain statistically valid national results, survey results from the three regions were weighted according to the proportion of total U.S. corn acres in each region. The targeted regions are outlined below:

A. Eastern Corn Belt: Illinois, Indiana, Kentucky, Michigan, Ohio, Pennsylvania, Tennessee (excluding cotton region counties), Virginia (excluding cotton region counties), Wisconsin

B. Western Corn Belt: Iowa, Kansas, Minnesota, Missouri (excluding cotton region counties), North Dakota, Nebraska, Oklahoma (excluding cotton region counties), South Dakota, Texas (excluding cotton region counties)

C. Cotton region: Alabama, Arkansas, Florida, Georgia, Louisiana, Missouri (cotton region counties only), Mississippi, North Carolina, Oklahoma (cotton region counties only), South Carolina, Tennessee (cotton region counties only), Texas (cotton region counties only), Virginia (cotton region counties only)

2. Results

A total of 1,019 growers completed the online survey in 2011 with 897 respondents from the Corn Belt and 122 from the cotton region. All of these growers met the criteria that included size requirements for total corn acres and minimum acres of Bt corn. The number of growers completing the survey met overall targets for each of the identified geographic regions.

[5] EPA Review of ABSTC's 2007 and 2008 Corn IRM CAP (April 15, 2009).
[6] Minutes of Meeting between BPPD and the ABSTC IRM Stewardship Subcommittee to Discuss 2007 and 2008 IRM CAP Reports (submitted by Stanley H. Abramson on behalf of the members of the ABSTC IRM Stewardship Subcommittee to Mr. Mike Mendelsohn on August 4, 2009).

a. Grower Adherence with Refuge Size Requirements

As described in Sec. II,1, Methodology, above, the Grower Survey captured data on an individual product basis, allowing Market Probe to determine if a grower had fulfilled the refuge requirements for each product planted on the grower's farm. As shown in Table 1, 87% (24% + 63%) of growers reported planting some or all of the required refuge. The majority of growers (63%) reported that they fully met the refuge size requirement for all Bt corn products planted on their farms, while an additional 24% of growers reported that they partially met the refuge size requirement. Overall, 13% of growers responded that they planted only Bt corn products on their farm and planted no refuge. Adherence to refuge size requirements by Bt corn growers in the cotton region was consistently lower than adherence by Bt corn growers in the two Corn Belt regions.

Table 1. Grower adherence with the refuge size requirement by region

% of Growers Surveyed Who:	All Regions Combined (n=1,019)[1]	Eastern Corn Belt (n = 283)[1]	Western Corn Belt (n=614)[1]	Cotton Region (n=122)[1]
Met refuge size requirement	63%	68%	66%	39%
Partially met refuge size requirement	24%	20%	24%	38%
Planted no refuge acres	13%	12%	10%	23%

[1]The margin of error for the results for refuge size is: 3.1% (All regions); 5.7% (East), 3.8% (West), 8.8% (Cotton).

The survey data, separated into corn borer refuge size and corn rootworm refuge size, are presented in Table 2. These results show the percentage of growers who planted: (i) the correct refuge size for all of their corn borer-protected Bt corn (that might or might not have been stacked with corn rootworm traits) and, (ii) the correct refuge size for all of their corn rootworm-protected Bt corn (that might or might not have been stacked with corn borer traits). As with overall refuge size, adherence to refuge size requirements by trait type (corn borer or rootworm) was greater for the Corn Belt than for the cotton region. For corn borer-protected Bt corn, 66% of growers reported that they planted all of the required refuge acres, while an additional 18% reported planting at least some refuge. For corn rootworm-protected Bt corn, 72% of growers reported that they planted all required refuge acres, and an additional 12% reported partially meeting the required refuge acres.

Table 2. Grower adherence with the refuge size requirement by region and target pest

Percentage of Growers Surveyed Who:	All Regions Combined(n=1,009)	Eastern Corn Belt(n=280)	Western Corn Belt(n=608)	Cotton Region(n=121)
Corn borer refuge[1]				
Met refuge size requirement	66%	71%	68%	42%
Partially met refuge size requirement	18%	14%	18%	26%
Planted no refuge acres	16%	15%	14%	32%
Percentage of Growers Surveyed Who:	All Regions Combined (n=885)	Eastern Corn Belt (n=255)	Western Corn Belt (n=535)	Cotton Region (n=95)
Corn rootworm refuge[2]				
Met refuge size requirement	72%	73%	77%	40%
Partially met refuge size requirement	12%	11%	10%	26%
Planted no refuge acres	16%	16%	13%	35%

[1] Corn borer, with or without rootworm. The margin of error for the results for the corn borer refuge size is: 3.1% (All regions); 5.7% (East), 3.7% (West), 8.8% (Cotton).

[2] Corn rootworm, with or without corn borer. The margin of error for the results for the corn rootworm refuge size is: 3.2% (All regions); 6.0% (East), 4.0% (West), 9.9% (Cotton).

b. Grower adherence with the refuge distance requirements

As described in Sec. II,1, Methodology, above, all growers were required to provide information regarding distance of the planted refuges for up to three products. For determining adherence to distance requirements on a whole farm basis, data for the growers who planted three or fewer products were included. As presented in Table 3, 790 growers surveyed planted three or fewer Bt corn products on their farm. Sixty percent (60%) of these growers reported that they met the refuge distance requirement for all of the Bt corn products on their farm. Overall, grower adherence with refuge distance requirements was higher in the Corn Belt than the cotton region and higher for corn borer refuge (that can be planted up to ½ mile away from corn borer-protected Bt corn) than for the corn rootworm refuge (that must be planted within or adjacent to rootworm-protected Bt corn).

Table 3. Grower adherence with the refuge distance requirement by region and target pest for growers who planted one to three Bt corn products

	All Regions	Eastern Corn Belt	Western Corn Belt	Cotton Region
Growers[1] adhering to distance requirement for all fields:	All products on farm[2]			
	60% (n=790)	61% (n=214)	64% (n=465)	44% (n=111)
	Corn borer-protected Bt corn[3]			
	76% (n=754)	81% (n=199)	79% (n=447)	59% (n=108)
	Corn rootworm-protected Bt corn[4]			
	61% (n=630)	62% (n=172)	66% (n=376)	38% (n=82)

[1]Only growers who planted no more than 3 products were queried on both size and distance compliance.
[2]The margin of error for the results for refuge distance is: 3.4% (all regions); 6.6% (East), 4.4% (West), 9.2% (Cotton).
[3]Corn borer, with or without rootworm. The margin of error for the results for the corn borer refuge distance is: 3.4% (All regions); 6.8% (East), 4.4% (West), 9.3% (Cotton).
[4]Corn rootworm, with or without corn borer. The margin of error for the results for the corn rootworm refuge distance is: 3.7% (All regions); 7.4% (East), 4.9% (West), 10.7% (Cotton).

While the survey results above represent refuge adherence across entire farms, analyzing the refuge distance requirement data on a field basis rather than a grower basis presents a more appropriate measure of the resistance risk. Table 4 presents the percentage of fields meeting the refuge distance requirement for both corn borer-protected Bt corn (1/2 mile refuge distance requirement) and corn rootworm-protected Bt corn (within or adjacent refuge distance requirement) on a field basis. The field-by-field analysis provides higher resolution of refuge practices on the farm. For example, a grower who has three fields, two of which meet the refuge requirements and one of which does not, is counted as not adhering to refuge requirements on a whole farm basis (Table 3). The field-by-field analysis shown in Table 4 represents a more biologically relevant measure of refuge distance adherence than the whole farm analysis because the whole farm analysis does not account for all fields that meet the distance requirements. As shown in Table 4, overall 81% of the corn borer-protected Bt cornfields had refuge planted meeting the distance requirement (within ½ mile), while 70% of the corn rootworm-protected Bt cornfields had refuge within or adjacent to the field.

Table 4: Fields meeting refuge distance requirement for each region and target pest (fields on farms planting up to three Bt corn products on their farm)

Adherence with distance requirement for individual Bt corn fields	All Regions	Eastern Corn Belt	Western Corn Belt	Cotton Region
Corn borer-protected Bt corn[1]	81% (n=6,308)	85% (n=2,226)	85% (n=3,307)	54% (n=775)
Corn rootworm-protected Bt corn[2]	70% (n=4,686)	72% (7=1,726)	76% (n=2,418)	37% (n=542)

[1] Corn borer, with or without rootworm. The margin of error for the results for the corn borer refuge distance is: 1.2% (All regions); 2.1% (East), 1.7% (West), 3.5% (Cotton)..
[2] Corn rootworm, with or without corn borer. The margin of error for the results for the corn rootworm refuge distance is: 1.4% (All regions); 2.3% (East), 2.0% (West), 4.2% (Cotton).

c. Grower Awareness of IRM Requirements and IRM Education

Almost all growers surveyed (98%) indicated they were aware of refuge requirements for managing insect resistance. There was a small difference between the Corn Belt (98%) and the cotton region (92%), but the overall awareness of refuge requirements was high for all regions. Ninety-five percent (95%) of growers stated that insect resistance management plans for Bt corn are somewhat or very important, and this number was similar for the Corn Belt (95%) and the cotton region (93%).

The percentage of growers acknowledging that they had enough IRM information at planting (98%) was higher in the Corn Belt than that for growers in the cotton region (87%). When IRM awareness options were presented, the majority of growers (71%) said that the seed dealer was the most-used source of information for refuge requirements. Product use guides and seed company representatives were also widely consulted at 42% and 41%, respectively. Growers indicated that they are receiving multiple sources of IRM information with 75% citing face-to-face meetings, 72% citing postcards and 57% citing information provided on the seed bag or tag.

d. Discussion

The Grower Survey has shown that growers consider IRM and the use of refuges to be important practices when growing Bt corn. Nearly all growers reported multiple sources of IRM information and that they had sufficient information at the time of planting about refuge requirements. The high percentage of fields that are planted with a refuge indicates that resistance management is practiced across most of the Corn Belt. Growers are making a good faith effort to fulfill their refuge requirements; however, as in previous years, the survey continues to indicate that a significant number of growers do not adhere to refuge requirements for all their Bt corn fields, and a small number of growers fail to plant any refuge. Inadvertent errors, logistical issues, weather conditions, and risk of yield and economic loss were often cited by growers as factors contributing to non-compliance.

In the cotton region, adherence to refuge requirements continued to be lower than in the Corn Belt. The ABSTC is undertaking a project to better understand the biological importance of refuge implementation in the cotton region, with a focus on corn earworm.

Section III. Third-Party IRM On-Farm Assessments

1. Methodology

The objective of the IRM On-Farm Assessment program is to look for individual growers who are out of compliance with refuge requirements and provide education and assistance to those found so that they are better able to follow refuge requirements. Unlike the IRM Grower Survey, the On-Farm Assessment program is not a statistical tool for measuring the level of adherence with the IRM requirements. Throughout the On-Farm Assessment process, identifying details of the assessed growers are kept confidential by the registrant contracting the assessment.

All Bt corn products that require a structured refuge were included in the 2011 IRM On-Farm Assessment program. Each registrant used a similar IRM assessment form with company-specific sections customized to suit the needs of each registrant. The actual grower assessment questions were consistent across registrants.

The On-Farm Assessment program in 2011 included the following new elements:

- Contract with independent third parties to perform on-farm assessments of adherence with refuge requirements
- Focus the majority of the on-farm assessments in regions where the risk of resistance is greatest
- Use available Bt sales records and other information to refine grower lists for on-farm assessments

Third-party contractors were trained on objectives and mechanics of the data collection process prior to initiating the 2011 On-Farm IRM Assessment process. As in previous years, the training was conducted through a variety of mechanisms (e.g., face-to-face meetings and electronic presentations) and included the key elements of the On-Farm IRM Assessment program (e.g., steps to complete the assessment form, messages to growers, and follow-up actions).

The selection pressure for resistance and the consequences of resistance are expected to be greatest in regions where adoption of Bt corn technology is greatest and where key target insect pest pressure is greatest. Compliance with refuge requirements is therefore most critical in these regions. In 2011, approximately two-thirds of the growers scheduled for an assessment were selected from areas where pest resistance risk is highest (based on high Bt corn penetration and target pest pressure) and where historical non-compliance has been reported, including states in both the Corn Belt and the cotton region. The remaining growers were randomly selected in areas where the registrants' Bt corn products are sold. Geographically focusing the assessments in areas of highest pest

resistance risk helps the registrants identify and correct incidents of non-compliance most critical to product durability.

In accordance with the enhanced CAP, a tiered On-Farm Assessment process was implemented. Each member company independently reviewed available sales data for all its Bt corn customers and identified individual growers who, according to these purchase records, may have purchased little or no refuge seed. The Bt product registration terms and conditions mandate that this purchase-based screening be done to identify growers who may not be compliant with refuge requirements. The EPA's rationale for changing the terms and conditions was to increase the probability of identifying non-compliant growers. Each registrant shared this information on a confidential basis with independent third parties conducting the on-farm assessments. The third parties conducted "first time" on-farm assessments (i.e., growers had not been assessed the previous year) to gather planting information that registrants use to determine whether individual growers were in compliance with refuge requirements and the extent of any deviations. Growers selected included a range of farm sizes. Based on assessment results of an individual grower who was found to be non-compliant, a compliance assistance program will be implemented to increase the grower's adherence to refuge requirements. Repeated non-compliance for refuge requirements will result in a grower being denied access to the registrant's Bt corn products.

First-time on-farm assessments were conducted for 3,053 growers in 2011. In addition to these first-time assessments, there were 395 growers who were re-assessed because they were found to be out of compliance in the 2010 on-farm assessments. The on-farm re-assessments were also conducted by independent third parties and followed the same approach as the first-time assessments.

On-farm assessments, both first-time and re-assessments, involved face-to-face discussion with growers about their plantings of Bt corn and refuge corn in 2011. Growers were encouraged to refer to invoices, planting records and field maps to ensure accurate responses. Assessed growers were asked to provide the number of acres planted to the registrant's Bt corn products and the number of refuge acres associated with those products. For each Bt corn field, assessed growers were asked about the proximity of refuge acres. Assessment forms were then reviewed for grower adherence with refuge requirements, and whether any non-compliance met the definition of significant non-compliance for the Bt corn product.

Registrants are addressing compliance deviations identified in 2011 according to the common set of standards outlined in the Phased Compliance Approach as identified in the 2011 enhanced CAP (MRID 48375101). Examples of materials used as part of this follow-up process (e.g., educational material, warning letters and the compliance

assistance contact form) have been provided to the EPA in previously submitted annual CAP reports.

2. Results

a. Results of First Time On-Farm Assessments in 2011

In 2011, all Bt corn product types that required a structured refuge, regardless of their refuge size requirement, were included in the On-Farm Assessment process for all trait registrants. It is important to note that the number of on-farm assessments conducted on an individual grower may vary as more than one product type may be assessed with a grower. Prior to 2011, results for on-farm assessments were consolidated on an assessment basis, not a grower basis. In 2011, on-farm assessment results have been consolidated on a grower basis rather than on an assessment or product type basis. Reporting information on a grower basis helps registrants provide education to seed dealers and growers across their product portfolios and increase focus in areas where higher incidences of non-compliance occur.

As previously noted, each registrant developed a confidential list of growers eligible for assessment by a third party. The lists were created based on grower purchase records, with growers selected who had purchased insufficient refuge from the registrant to support the purchased Bt corn products. As anticipated, the targeted grower selection process resulted in more assessments indicating non-compliance than in previous years. A total of 1,242 growers were identified as non-compliant with at least one refuge requirement, of which 805 growers had a deviation that met the definition of significant. Registrants are addressing these deviations with each grower.

b. Results of On-Farm Re-assessments of Growers Found to be Out of Compliance in 2010

In accordance with the Phased Compliance Approach, 395 growers who were found out of compliance in 2010 were re-assessed in 2011. Of the 257 growers who met the definition of significant non-compliance in 2010, four of these growers were also significantly non-compliant in 2011. In accordance with EPA requirements, these growers have been denied access to the registrant's Bt corn products for the 2012 planting season.

c. Discussion

The tiered approach to the On-Farm Assessment program, whereby purchase records were reviewed for all Bt corn customers and a targeted selection of growers received on-farm assessments, resulted in identifying more than three times as many non-compliant growers in 2011 than previous years. To continue to improve grower adherence with

refuge requirements, these growers will receive compliance assistance in 2012 and will also be re-assessed in 2012.

As with previous years, some key refuge implementation challenges were identified by growers during the On-Farm Assessment process. Some growers incorrectly calculated refuge acres, resulting in non-compliance. For example, growers may have calculated refuge acres for a 20% refuge product by multiplying the number of Bt corn acres by 20%, resulting in only a 16.7% refuge. Other growers who planted a combination of products with differing refuge requirements appeared to miscalculate the total required refuge size. Registrants are focusing their education efforts in 2012 to address such calculation errors by promoting the use of the NCGA IRM Calculator (www.irmcalculator.com). Other primary reasons for non-compliance provided by growers in 2011 were similar to those provided in previous years:

- Weather-related issues (e.g., rain prevented the grower from planting planned refuge)
- General awareness (e.g., grower misunderstood/unaware of refuge requirements)
- Dealer-related issues (e.g., refuge seed not delivered, preferred non-Bt hybrids not available)
- Inadvertent grower errors (e.g., planting errors)
- Logistical issues (e.g., small Bt corn field size and significant spacing between Bt corn fields made meeting refuge requirements for all fields a challenge)

These findings continue to highlight the need to enhance the refuge education program throughout the seed delivery channel, such as calculating the total refuge needed on the farm. The registrants are also optimistic that including the refuge size requirements on seed packaging, e.g. bags, bag tags, or hard-sided seed containers) in the 2012 planting season will help address growers' refuge awareness and understanding at the time of planting.

As a result of the compliance assistance education given to non-compliant growers identified in 2010, the majority of growers re-assessed in 2011 were found to be planting an appropriate refuge. In accordance with the criteria for grower license revocation, four growers will be denied access to the registrant's Bt corn technologies for the 2012 planting season. The Phased Compliance Approach has again proven to be an effective mechanism to correct the vast majority of individual instances of non-compliance with IRM requirements identified through the On-Farm Assessment program.

Section IV. Tips and Complaints

The registrants have mechanisms (e.g. toll-free customer service numbers) to receive information regarding alleged instances of non-compliance with the IRM requirements. The availability of these mechanisms continues to be communicated to growers, seed

dealers and sales representatives as part of the IRM education programs. In 2011, the registrants collectively received two tips and complaints. Legitimate tips and complaints (as defined in Section 5.a of the enhanced CAP) were managed in accordance with the CAP requirements. The growers identified through the tips and complaints process received an on-farm assessment. If the grower was found to be out of compliance during this assessment, the grower was treated in a manner consistent with the Phased Compliance Approach.

Section V. Publicizing the Compliance Assurance Program

The registrants have widely publicized the CAP, including the Phased Compliance Approach, which is common to all Bt corn registrations to ensure growers are aware of the On-Farm IRM Assessment program and the penalties for non-compliance, including revocation of access to Bt technologies. The key elements of the CAP and Phased Compliance Approach are well integrated into each registrant's IRM education program, including company literature, internal training sessions and meetings with growers and dealers. In addition, key stakeholder groups such as the National Corn Growers Association are educated by the ABSTC members and continue to inform their members of the CAP. Consistency of the CAP for all Bt traits in corn that provide protection from corn borers and/or corn rootworms, including those products with pyramided traits, that require growers to plant a structured refuge, strengthens awareness.

Section VI. Conclusions

A new enhanced CAP was implemented in 2011 and this is the first report under the new CAP requirements. As in previous years, the compliance assurance activities for Bt corn continue to be effective. This report includes a summary of the 2011 results for the third-party Grower Survey, third-party On-Farm Assessments, and CAP activities. Methodology changes to the IRM Grower Survey, as well as the IRM On-Farm Assessments, were implemented to comply with registration terms and conditions for the broad portfolios of products with differing refuge requirements. These changes, while necessary, preclude the direct comparison of data from the 2011 CAP report with data from previous CAP activities. The data in this report should therefore be considered the comparator for future CAP activities.

In 2011, the Grower Survey methodology was revised and expanded to incorporate the broad portfolios of Bt corn products with differing refuge requirements. A statistically representative sample of growers was surveyed. The results from the survey for grower adherence to refuge requirements for corn borer and corn rootworm products are similar. A regional analysis of the Grower Survey results presented no clear differences in adherence to the refuge requirements between growers in the eastern and western Corn Belt; however, the growers in the cotton region showed lower levels of adherence. In addition, growers in the cotton region more frequently failed to plant any refuge. On a

field basis, the survey found that 81% of corn borer-protected Bt corn fields and 70% of corn rootworm-protected Bt corn fields were associated with a refuge within the required distance.

The objective of the On-Farm IRM Assessment program is to look for individual growers who are out of compliance with refuge requirements and provide education and assistance to those found so that they are better able to follow refuge requirements. Unlike the IRM Grower Survey, the On-Farm Assessment program is not a statistical tool for measuring the level of adherence with the IRM requirements. The enhanced CAP resulted in several changes focused on the On-Farm Assessment process. The enhancements that were developed were consistent with four principal objectives: 1) increase focus and actions on areas where non-compliance with refuge requirements poses the greatest risk; 2) increase refuge compliance over time in areas of greatest risk; 3) increase on-farm assessments of growers that are not planting refuges; and 4) avoid creating unreasonable costs and requirements for growers planting sufficient refuges. The enhanced CAP represents a balanced approach towards meeting these four objectives. The changes extend the registrants' ability to identify incidents of non-compliance that may create resistance risks and to work with growers involved to bring them back into compliance.

Each member company independently reviewed available sales data for all of their Bt corn customers. As required by terms and conditions of Bt product registrations, On-Farm Assessments were conducted with growers who, according to these sales records, may not have purchased sufficient refuge seed to determine whether they were in compliance with refuge requirements and the extent of any compliance deviations. As anticipated, using a tiered grower selection process for On-Farm Assessments identified more than three times as many non-compliant growers than in years past. In accordance with the CAP's Phased Compliance Approach, all growers who were found out of compliance in 2010 were contacted with additional educational materials and a follow-up re-assessment in 2011, which resulted in the majority complying with the requirements during the 2011 growing season. While repeat non-compliant growers were denied access to the registrant's Bt corn products, the Phased Compliance Approach has again proven to be an effective mechanism to correct the vast majority of individual instances of non-compliance identified through the On-Farm Assessment program.

As with previous years, some key refuge implementation challenges were identified by growers during the On-Farm Assessment process. Some growers incorrectly calculated refuge acres, resulting in non-compliance. For example, growers may have calculated refuge acres for a 20% refuge product by multiplying the number of Bt corn acres by 20%; resulting in only a 16.7% refuge. Other growers who planted a combination of products with differing refuge requirements appeared to miscalculate the total required refuge size. Registrants are focusing their education efforts in 2012 to address such

calculation errors by promoting the use of the NCGA IRM Calculator (www.irmcalculator.com).

These findings continue to highlight the need to enhance the refuge education program throughout the seed delivery channel, including calculating the total refuge needed on the farm. The registrants are also optimistic that including the refuge size requirements on seed packaging in the 2012 planting season will help address growers' refuge awareness and understanding at the time of planting.

As in previous years, the Grower Survey indicated that adherence with refuge requirements in the cotton region was lower than in the Corn Belt. Factors contributing to lower adherence in that region include the larger required refuge size, smaller field sizes, more diverse cropping systems, and greater complexity of operations. Education programs continue to highlight the specific refuge requirements in this region, and the On-Farm Assessment program included key parts of this region, providing the opportunity to correct individual instances of non-compliance for future growing seasons. It is important to note that the cotton region represents less than 10% of the US corn acres (NASS 2009); however, the cotton region will receive increased focus for On-Farm Assessments. ABSTC is also undertaking a project to understand the biological importance of refuge implementation in the cotton region, with a focus on corn earworm.

Implementation of the enhanced CAP demonstrates the industry's commitment to Bt corn product stewardship so that growers can continue benefitting from Bt corn technologies.

Reference:

ABSTC. 2011. Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer-Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer/Corn Rootworm Protected Stacked Bt Corn. MRID No. 48375101. 20 p.

NASS, 2009: http://usda01.library.cornell.edu/usda/nass/Acre//2010s/2010/Acre-06-30-2010.txt

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Appendix

Bt Corn Registrant Product Information

Product Name	*Event name*	*Registration Number*	*Active Ingredient*
Syngenta Agrisure® GT/CB/LL[7]	Bt11	67979-1	Cry1Ab
Monsanto YieldGard® Corn Borer[8]	MON 810	524-489	Cry1Ab
Dow AgroSciences Herculex® I[9]	TC1507	68467-2	Cry1F
Pioneer Herculex® I	TC1507	29964-3	Cry1F
Monsanto YieldGard VT Rootworm/RR2®	MON 88017	524-551	Cry3Bb1
Monsanto YieldGard VT Triple®	MON 88107 × MON 810	524-552	Cry3Bb1 + Cry1Ab
Dow AgroSciences Herculex® RW	DAS-59122-7	68467-5	Cry34Ab1/Cry35Ab1
Pioneer Herculex® RW	DAS-59122-7	29964-4	Cry34Ab1/Cry35Ab1
Dow AgroSciences Herculex® Xtra	DAS-59122-7 + TC1507	68467-6	Cry34Ab1/Cry35Ab1 + Cry1F
Pioneer Herculex® Xtra	DAS-59122-7 + TC1507	29964-5	Cry34Ab1/Cry35Ab1 + Cry1F
Syngenta Agrisure® RW	MIR604	67979-5	mCry3A
Syngenta Agrisure® 3000GT	Bt11 x MIR 604	67979-8	Cry1Ab + mCry3A
Syngenta Agrisure Viptera™ 3110	Bt11 x MIR162	67979-12	Cry1Ab + Vip3Aa20
Syngenta Agrisure Viptera™ 3111	Bt11 x MIR162 x MIR604	67979-13	Cry1Ab + Vip3Aa20 + mCry3A
Syngenta Agrisure Viptera™ 3220	Bt11xMIR162xTC1507	67979-15	Cry1Ab + Vip3Aa20 + Cry1F
Monsanto Genuity™ VT Double PRO	MON 89034	524-575	Cry1A.105 + Cry2Ab2
Monsanto Genuity™ VT Triple PRO	MON 89034 × MON 88017	524-576	Cry1A.105 + Cry2Ab2 + Cry3Bb1
Monsanto Genuity® SmartStax®	MON 89034 × TC1507 × MON 88017 × DAS-59122-7	524-581	Cry1A.105 + Cry2Ab2 + Cry1F + Cry3Bb1 + Cry34Ab1/Cry35Ab1
Dow AgroSciences SmartStax®	MON 89034 × TC1507 × MON 88017 × DAS-59122-7	68467-7	Cry1A.105 + Cry2Ab2 + Cry1F + Cry3Bb1 + Cry34Ab1/Cry35Ab1
Syngenta Agrisure™ 3122 Refuge Renew	Bt11 x DAS-59122-7 x MIR604 x TC1507	67979-17	Cry1Ab + Cry34Ab1/Cry35Ab1 + mCry3A + Cry1F
Monsanto Genuity® SmartStax® RIB Complete™	Seed blend of MON 89034 × TC1507 × MON 88017 × DAS-59122-7and 5% non-Bt seed	524-595	Cry1A.105 + Cry2Ab2 + Cry1F + Cry3Bb1 + Cry34Ab1/Cry35Ab1
Dow AgroSciences Refuge Advanced Powered by SmartStax®	Seed blend of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-Bt seed	68467-16	Cry1A.105 + Cry2Ab2 + Cry1F + Cry3Bb1 + Cry34Ab1/Cry35Ab1
Monsanto YieldGard® RW	MON863	524-528	Cry3Bb1
Monsanto YieldGard® Plus	MON810 x MON863	524-545	Cry1Ab + Cry3Bb1

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[7] Agrisure, Agrisure RW, Agrisure CB/LL, and Agrisure CB/LL/RW are registered trademarks of Syngenta Seeds, LLC; Ignite®, LibertyLink® and the Water Droplet logo are registered trademarks of Bayer.

[8] YieldGard, Roundup Ready, YieldGard VT Rootworm/RR2, YieldGard VT Triple, Genuity, VT Double PRO, VT Triple PRO, SmartStax and RIB Complete are trademarks of Monsanto Technology, LLC.

[9] Herculex® Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred, a DuPont business. Herculex® is a registered trademark of Dow AgroSciences LLC.